Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

T-750M

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-46

April 20, 1998

Mr. Lawrence Evans, President/CEO
MedX96, Inc.
1401 NE 77th Street
Ocala, FL 34479

Dear Mr. Evans:

We are writing to you because on March 24 and 25, 1998 FDA Investigator Ronald T. Weber collected information that revealed serious regulatory problems involving medical exercise machines which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (The Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

The inspection revealed that the device is adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the Current Good Manufacturing Practice (GMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to establish and document a formal quality assurance program, e.g., most procedures are not completed and approved (FDA 483, Item #1).

- Failure to establish and implement adequate record keeping procedures, e.g., there are no established, written Device Master Records except for device specification drawings and there are no Device History Records documenting the manufacture of each device or group of devices (FDA 483, Item #2).

- Failure to validate significant manufacturing processes and quality assurance tests, e.g., soldering of printed circuit boards (PCBs) and welding of frames to ensure all specifications are met (FDA 483, Item #3).

- Failure to establish and implement an adequate complaint handling program, e.g., there are no written procedures or records of investigation and your firm has not defined a complaint for the purposes of receipt, investigation, and follow-up (FDA 483, Item #4).

- Failure to document, review, approve, implement and validate changes to components, finished devices, labeling, packaging or manufacturing process specifications, e.g., there are no written procedures and changes are not verified or validated to assure that all specifications are met and that they will not adversely affect the product (FDA 483, Item #5).

- Failure to establish and document written MDR procedures.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Inspectional Observations (FDA 483), issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. We note that you have promised correction to all noted violations by April 1, 1998. Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the Good Manufacturing Practice and the Quality System Regulations and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at http://www.fda.gov.

If you have more specific questions about the Quality System Regulation and how it affects your particular devices, or about the content of this letter, please contact Tim Couzins at (407) 475-4728.

Sincerely,

Douglas D. Tolen
Director, Florida District